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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,021	01/17/2002	Paul A. Moore	PZ016P2	2187

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EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.M.

Office Action Summary**Application No.**

10/047,021

Applicant(s)

MOORE ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11-13, 16, 17, 19, 20 and 23-55 is/are pending in the application.
- 4a) Of the above claim(s) 1, 13, 17, 19, 20 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 16 and 24-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/4/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election of Group II, claims 11, 12, 16, and 24-55 and SEQ ID NO: 86 in the response filed December 4, 2003, pages 8-10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants did not address the search of Group VII, claim 23 which is drawn to a product of an assay method, the nature of which product is undisclosed in the application (see MPEP 818.03(a)). In addition, applicant's arguments in connection with the search of claims directed to polypeptides, nucleic acids, and antibodies as requiring no undue burden are not convincing. Separate search queries in multiple databases would be required to adequately search all of the inventions. Applicants acknowledge that a search of polypeptides would not completely cover the prior art for either nucleic acids nor antibodies. Since not all of the prior art would be covered by a search for the polypeptides, then other searches would be necessary. These additional searches constitute an undue burden on USPTO resources.

Claims 1, 13, 17, 19, 20, and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed December 4, 2003.

The disclosure is objected to because of the following informalities.

- (a) In paragraph 398, line 7, "second" is a typographical error.

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Embedded hyperlink and/or other form of browser-executable code occur in at least the following locations:

- (a) page 324, line 3 and
- (b) page 351, line 18.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 12, 16, 30-35, and 41-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) Claim 11 is indefinite because "Y" is not defined. There is no provision for a claim to refer to a table in the specification.
- (b) Claim 11 is indefinite because "Z" is not defined. There is no provision for a claim to refer to a table in the specification.
- (c) Claim 11 is indefinite because "X" is not defined. There is no provision for a claim to refer to a table in the specification.
- (d) Claim 11 is incomplete because it requires unknown ATCC deposits.
- (e) The recitation of "polypeptide fragment" (claim 11(a) and (b)) is vague and indefinite because no lower limit is set for the fragment size.
- (f) The recitation of "having biological activity" (claim 11(b)) is vague and indefinite because no particular activity is mentioned in the claim.
- (g) The recitation of "polypeptide domain" (claim 11(c)) is vague and indefinite because it is not clear how much of the SEQ ID NOs sequence constitutes a domain.

- (h) The recitation of "polypeptide epitope" (claim 11(d)) is vague and indefinite because it not clear how much of the polypeptide sequence constitutes an epitope.
- (i) The recitation of "secreted form" (claim 11(e) and claim 12) is vague and indefinite because the instant application does not disclose or define a secreted form of the sequence encoded in any particular ATCC Deposit.
- (j) The recitation of "full length protein" (claim 11(f) and claim 12) is vague and indefinite because the instant application does not disclose or define a full length protein of any sequence encoded in any particular ATCC Deposit.
- (k) The recitation of "a variant" (claim 11(g)) is vague and indefinite because the instant application does not define the boundaries of a variant.
- (l) The recitation of "comprises sequential amino acid deletions from either the C-terminus or the N-terminus" (claim 12) is vague and indefinite because the molecules cannot be defined by what they lack.
- (m) Claim 16 is incomplete because it depends from cancelled claim 15.
- (n) The recitation of "the secreted portion" (claims 30 and 43) is vague and indefinite because the secreted portion of ATCC Deposit No. 209224 is not defined in the application.
- (o) Claims reciting a percentage sequence identity to molecules encoded in ATCC Deposits (claims 11 and 41-45) are vague, indefinite, and incomplete because the sequence of the ATCC Deposits are not clear and are not definitely disclosed. Thus, it is not possible for one of skill in the art to know what the metes and bounds of the claims are.
- (p) Claims reciting fragments of molecules encoded in ATCC Deposits (claims 11, 31-33, and 35) are vague, indefinite, and incomplete because the sequence of the ATCC Deposits are not clear and are not definitely disclosed. Thus, it is

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not possible for one of skill in the art to know what the metes and bounds of the claims are.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11, 12, 16, and 24-55 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. There is no specific, substantial, and credible utility disclosed for SEQ ID NO: 86 or claimed fragments or variants thereof. The lists on pages 40-42 are no more than vague hoped for uses that those of skill in the art might hunt for in order to use the claimed polypeptides. They are not a disclosure of specific, substantial, and credible utilities for an invention in its current (*i.e.* as of the filing date) form. See *Brenner v. Manson*, Supreme Court of the U.S., 148 USPQ 689 (1966).

Claims 11, 12, 16, and 24-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the rejection under 35 USC § 101 hereinabove is incorporated here.

Claims 11, 12, and 36-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those polypeptides for which a fixed sequence is disclosed, does not reasonably provide enablement for all of the polypeptides embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant application does not give one of skill in the art enough guidance to make and use polypeptides that are not of a disclosed fixed sequence that has activity. The Court of Appeals for the Federal Circuit found that claims reciting polypeptides with multiple amino acid substitutions were broader than the enabling disclosure. See *Amgen v. Chugai* (18 USPQ2d 1016, Fed. Cir. 1991)). *Amgen* applies here because the

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instant application gives no guidance to those of skill in the art as to how to make and use sequence variants that fall within the scope of the claims. It is noted that the court alluded to at least some evidence of this sort in *Amgen* (*e.g.*, see page 1027, column 2, first full paragraph). The instant application gives even less guidance than in *Amgen*.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zuellig et al (Eur. J. Biochem. 204: 453 (1992)). Zuellig et al discloses a polypeptide that has some amino acids in common with SEQ ID NO: 86 (see the alignment in Appendix A). Claim 11 is broad enough to embrace the polypeptide of Zuellig et al (*e.g.*, parts (a)-(d) and (g) of claim 11 are drawn to polypeptides that comprise only fragments, domains, epitopes, or variants of SEQ ID NO: 86).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

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PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is
(703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should
be directed to the receptionist whose telephone number is (571) 272-1600.



**James Martinell, Ph.D.
Primary Examiner
Art Unit 1631**

Attachment: Appendix A